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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,652	04/30/2001	Akihiro Kondo	KONDO 7	1863

EXAMINER
CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
1637	

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DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,652	KONDO ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made for the request to establish continued prosecution application (RCE) filed on January 18, 2005. The request for RCE is accepted and is established with the status of the application as follows: the filling date of this RCE is established as April 30, 2001; Applicants' response to the earlier office action filed along with RCE is considered and has been entered.

Status of the Application

2. The action is in response to the RCE filed on January 18, 2005. Currently claims 13-14 are pending. Claims 1-12 are cancelled. All arguments and amendment have been fully considered and thoroughly reviewed and deemed persuasive.

3. With regard to the objection made in the previous office action to claim 13, Applicants' amendment and arguments are fully considered and the objection is withdrawn herein in view of the amendment.

4. With regard to the rejection under 35 USC 112, second paragraph, Applicants' arguments and amendment are fully considered and the rejection is withdrawn in view of amendment.

5. With regard to the rejection under 35 USC 103(a), Applicants' arguments and amendment are fully considered and the rejection is withdrawn herein in view of the amendment and new grounds of rejections.

New Grounds of rejections

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims recite "known" genes, the meets and bounds of the claims are unclear, that is, it is not clear what the term "known" indicates, does it represent genes known to one skilled in the art or genes known to examiner or genes known to public in general.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Note: The preamble of the claim 13 is drawn to a method for determining a signal transduction pathway that is influenced by an endocrine activity of a test compound, herein endocrine disrupting activity is interpreted as an inherent property of the test compound, since the influence of the test compound alters the genes involved in a signaling pathway.

Claim13 is rejected under 35 U.S.C. 102(a) as being anticipated by Ollila et al. (Biochem. Biophy. Res. Commun., Vol. 249, pp. 475-480, 1998).

Ollila et al. teach a method of claims 13 and 14, for determining a signal transduction pathway gene expression, that is influenced by an endocrine disrupting activity of a test substance (OTK3 or anti-IgM) comprising

(a) exposing a cell (Jurkat (T-cell) or Ramos (B-cell) cells) to a test substance (OTK3 or anti-IgM) (see page 476, col. 1, lines 1-7);

(b) isolating a first mRNA from the cell that has been exposed to the test substance (see page 476, col. 1, line 1-9) and a second mRNA from a cell that has not been exposed to the test substance (unstimulated) (see page476, col. 1, line 1-9);

(c) hybridizing the mRNAs (first and second probes) with genes or DNA fragments derived from genes on a DNA array (cDNA expression array), wherein the first and second probes are obtained by labeling nucleic acids prepared using the first and second mRNA as templates (reverse transcription) (see page 476, col.1, paragraph 1 under the sub- heading hybridization analysis);

(d, e) comparing and identifying a series of genes in which the expression levels are altered as a result of exposure of cell to the test compound (see page 476, col.1, paragraph 1 under the sub- heading hybridization analysis).

(f) determining a series of genes involved in a signal transduction pathway, wherein the genes on the DNA array consists of known genes for each of the respective groups 1 to 17 (see page 476, col. 1, paragraphs 1-4 under results and discussion section, page 477, table 1, page 478, table-2).

Thus the disclosure of Ollila meets the limitations in the instant claim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ollila et al. (Biochem. Biophys. Res. Commun., Vol. 249, pages 475-480, 1998) in view of Lockhart et al. (USPN. 6,333,155).

Ollila et al. teach a method of claim14, for determining a signal transduction pathway gene expression, that is influenced by an endocrine disrupting activity of a test substance (OTK3 or anti-IgM) comprising

(a) exposing a cell (Jurkat (T-cell) or Ramos (B-cell) cells) to a test substance (OTK3 or anti-IgM) (see page 476, col. 1, lines 1-7);

(b) isolating a first mRNA from the cell that has been exposed to the test substance (see page 476, col. 1, line 1-9) and a second mRNA from a cell that has not been exposed to the test substance (unstimulated) (see page476, col. 1, line 1-9);

(c) hybridizing the mRNAs (first and second probes) with genes or DNA fragments derived from genes on a DNA array (cDNA expression array), wherein the first and second probes are obtained by labeling nucleic acids prepared using the first and second mRNA as

templates (reverse transcription) (see page 476, col.1, paragraph 1 under the sub- heading hybridization analysis);

(d, e) comparing and identifying a series of genes in which the expression levels are altered as a result of exposure of cell to the test compound (see page 476, col.1, paragraph 1 under the sub- heading hybridization analysis).

(f) determining a series of genes involved in a signal transduction pathway, wherein the genes on the DNA array consists of known genes for each of the respective groups 1 to 17 (see page 476, col. 1, paragraphs 1-4 under results and discussion section, page 477, table 1, page 478, table-2).

However, Ollila et al. did not teach identifying a test compound that causes disruption in a series of genes in a manner similar to an endocrine disruptor.

Lockhart et al. teach a method for screening and identifying compounds based on the similarities and differences in their effect on gene expression profiles using high density microarray analysis (see col. 6, line 47-59, col. 30, line 60-67, col. 31, line 1-24).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method for determining a signal transduction pathway influenced by an endocrine disrupting activity of a test substance as taught by Ollila et al. with incorporation of a step of screening or identifying compounds by microarray based monitoring of the gene expression profiles as taught by Lockhart et al. to achieve expected advantage of developing a an improved and sensitive molecular diagnostic method for identifying compounds that causes endocrine disruption in a similar manner to an endocrine disruptor. An ordinary skill in the art would have expected a reasonable success that said

combination would result in said expected advantage because drug screening methods using microarray based gene expression analysis was known at the time the invention was made as exemplified by Lockhart et al. An ordinary practitioner would have been motivated to modify the method as taught by Ollila et al. with the incorporation of a step of identifying a test compound based on monitoring gene expression profiles as taught by Lockhart et al. for the purpose of identifying a test substance on targeted monitoring of gene expression in a high-throughput assay.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Examiner
Art Unit 1637.

JEFFREY FREDMAN
PRIMARY EXAMINER
1/28/05